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No. 91-81

IN THE
Supreme Court of the United States
OCTOBER TERM, 1991

BARR LABORATORIES, INC.,
Petitioner,

v.

LOUIS W. SULLIVAN, Secretary of Health and Human Services, *et al.*,
Respondents.

Petition for Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

The Administrative Procedure Act provides that a "reviewing court shall . . . compel agency action unlawfully withheld." The question presented is whether a court that has found such unlawful witholding may refuse to grant relief to the aggrieved party.

PARTIES TO THE PROCEEDING

The parties to the proceeding below were the petitioner, Barr Laboratories, Inc., and the respondents, Louis W. Sullivan, Secretary of Health and Human Services, the Department of Health and Human Services, David A. Kessler, Commissioner, Food and Drug Administration, the Food and Drug Administration, Carl C. Peck, Director, Center for Drug Evaluation and Research, and the National Association of Pharmaceutical Manufacturers ("NAPM"). NAPM was an intervenor below.

The parties before this Court are the same as those in the proceeding below.

CERTIFICATION UNDER RULE 29.1

Barr Laboratories, Inc. has no parent or subsidiary companies.

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PETITION FOR WRIT OF CERTIORARI

Barr Laboratories, Inc. hereby prays that this Court grant a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit dismissing the petition in this case.

OPINIONS BELOW

The opinion of the court of appeals is reported at 930 F.2d 72 and is reproduced in the appendix hereto. App. 1a. Because this case involves a failure to act by the Food and Drug Administration, there is no administrative record to be reproduced.

JURISDICTION

The judgment of the Court of Appeals was entered April 16, 1991. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTES INVOLVED

21 U.S.C. § 355(j)(4)(A)[1]

> Within one hundred and eighty days of the initial receipt of an [Abbreviated New Drug Application] or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

5 U.S.C. § 706

> To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—
>
> (1) compel agency action unlawfully withheld or unreasonably delayed . . . .
>
> * * *

STATEMENT OF THE CASE

This dispute arises out of the continuing failure of the Food and Drug Administration ("FDA")[2] to comply with a statutorily mandated deadline for processing Ab-

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[1] This statute was enacted as section 505(j)(4)(A) of the Federal Food, Drug, and Cosmetic Act.

[2] The other federal respondents are the Department of Health and Human Services ("HHS"), which is the executive department of which the FDA is a part, the Secretary of HHS, the Commissioner of the FDA and the Director of the FDA's Center for Drug Evaulation and Research. The same relief is sought against each federal respondent, and for convenience this petition refers to the federal respondents collectively as "FDA."

breviated New Drug Applications ("ANDAs") filed by the petitioner, Barr Laboratories, Inc. ("Barr"). The Court of Appeals had jurisdiction over the FDA's inaction under 21 U.S.C. § 355(h), 5 U.S.C. § 706, 28 U.S.C. § 1331 and 28 U.S.C. § 1651.

The FDA is charged with pre-approving the safety and effectiveness of all prescription drugs sold in the United States. A new or "listed" drug is approved by the FDA pursuant to a New Drug Application ("NDA"). An NDA typically includes extensive data regarding the safety and effectiveness of the listed drug.

When a listed drug's patent protection expires or otherwise is lost, other pharmaceutical manufacturers have the right to produce "generic" versions of the drug. Barr is a manufacturer of generic drugs. Because the safety and effectiveness of each generic drug already has been determined by the FDA in the course of reviewing the NDA for the listed drug, the ANDA process does not require resubmission of such data. Instead the ANDA need only include data demonstrating that the generic drug is essentially the same as the listed drug.

Congress codified the ANDA process in 1984. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585. As the Court of Appeals put it, among the aims of Congress were "to get generic drugs into the hands of patients at reasonable prices—fast." App. 8a. Generic drugs are priced lower than their listed drug equivalents. The Court of Appeals said that

> for poorer people—the users for whom access to generic drugs is most important—a pecuniary saving on drugs may have important health benefits. The difference between sinking, say, 3% and 20% of one's income into pharmaceuticals spells a large difference in the range of economically accessible food and shelter.

App. 5a.

Intent on expediting the ANDA process, Congress required that "[w]ithin one hundred and eighty days of the initial receipt of an [ANDA] . . . , the [FDA] shall approve or disapprove the application." 21 U.S.C. § 355(j)(4)(A) (1988). This limitation was enacted despite the FDA's claim that the FDA would need a full year to process each ANDA. H.R. Rep. No. 857, Pt. 1, 98th Cong., 2d Sess. 19 (1984).

In recent years the FDA commonly has failed to meet the statutory deadline. App. 3a. Although the parties disagree as to the precise extent of this failure, the FDA did not dispute below that "the delays are severe," conceding that processing time for then-pending Barr ANDAs would "range from more than *double* the allotted time to nearly *quadruple*." *Id.* (emphasis the court's). On July 31, 1990, faced with steadily increasing injury due to the FDA's failure to observe the ANDA processing deadline, Barr petitioned the Court of Appeals for the D.C. Circuit for review of the FDA's failure to act on 23 Barr ANDAs that had been pending before the agency for more than 180 days.

Barr's petition advanced three separate and independent grounds for relief: that the FDA had unlawfully withheld action on Barr's ANDAs and thus violated both 21 U.S.C. § 355(j)(4)(A) and the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(1); that (in the event that the 180-day statutory deadline was not mandatory) the FDA had unreasonably delayed action on Barr's ANDAs and thus violated the second branch of section 706(1); and that the FDA's failure to act necessitated the issuance of a writ of mandamus under the All Writs Act, 28 U.S.C. § 1651. App. 10a-11a. Styled "Petition for Review of Agency Action Unlawfully Witheld and Unreasonably Delayed, and for Writ of Mandamus," the petition in its opening sentence sought "review of agency action unlawfully withheld and unrea-

sonably delayed by the respondents." App. 10a. Paragraph 1 of the petition stated that the Court of Appeals had jurisdiction under 21 U.S.C. § 355(h) and under the APA, adding that "[i]n a case within its jurisdiction, [the Court of Appeals] is authorized to issue a writ of mandamus by the All Writs Act." App. at 11a.[3]

The FDA opposed Barr's petition on various grounds. Among these were that the 180-day statutory deadline is not mandatory, that the FDA's tardiness is not sufficiently egregious to justify relief and that the pace of FDA's review is not unreasonable. The National Association of Pharmaceutical Manufacturers' ("NAPM") motion to intervene was granted by the Court of Appeals during the course of the proceeding below. NAPM, an association of generic drug manufacturers (not including Barr), essentially echoed Barr's arguments but asked that any relief granted by the court apply to all generic drug manufacturers that have experienced ANDA processing delays.

The Court of Appeals ruled that the 180-day ANDA processing deadline is mandatory and found that the FDA repeatedly has violated that deadline. App. 3a-4a. The Court of Appeals went on, though, to treat the Barr petition as limited to a request for a common law writ of mandamus:

> The issue before us, then, is not whether the FDA's sluggishness has violated a statutory mandate —it has—but whether we should exercise our equitable powers to enforce the deadline. Equitable relief, particularly mandamus, does not necessarily follow a finding of a violation: respect for the autonomy and comparative institutional advantage of the executive

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[3] The petition named as respondents all of the federal respondents in this Court. The altered caption appearing on the decision below, see App. 1a, was adopted by order of the Court of Appeals while the proceeding was pending there.

> branch has traditionally made courts slow to assume command over an agency's choice of priorities.

App. 4a.

Despite the mandatory language of the APA, the court evaluated Barr's case under a 1984 decision that sets out "six principles that have helped courts determine when *mandamus* is an appropriate remedy for agency delay." *Id.* (emphasis added) (citing *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70 (D.C. Cir. 1984)). Applying these principles, the court concluded that it either could not or should not

> reorder[] agency priorities. The agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way.
>
> * * *
>
> The agency could alleviate its own inefficiencies, perhaps through generic rulemaking or other simplifications of the review process—but judges have neither the capacity nor the authority to require such measures.

App. 7a, 8a (citation omitted).

In closing, the court conceded that the FDA is violating the letter and spirit of the law, and that "[t]here are probably remedies: more resources, more efficient use of those now committed, elimination of the residual effects of the recently publicized scandals [in the FDA's generic drug operations]." App. 8a-9a. The court nevertheless refused to act and dismissed Barr's petition. *Id.* Barr here seeks review of that dismissal.

REASON FOR GRANTING THE WRIT

THE COURT OF APPEALS' DECISION THAT THE ADMINISTRATIVE PROCEDURE ACT DOES NOT COMPEL RELIEF FOR UNLAWFULLY WITHHELD AGENCY ACTION PRESENTS AN IMPORTANT QUESTION OF FEDERAL LAW AND, IF NOT CORRECTED, WILL NULLIFY AN IMPORTANT PROVISION OF THE APA.

The APA states that when agency action has been unlawfully withheld, a reviewing court must compel that action. 5 U.S.C. § 706(1) (1988). The Court of Appeals ignored that language and ruled incorrectly that the APA does not require relief in such circumstances. Surprisingly, this Court never has decided this important question of federal law. That the D.C. Circuit is the forum for many important administrative law cases heightens the need for review of the decision below.

I. When a Reviewing Court Finds Unlawful Withholding of Agency Action, the APA Requires the Court to Compel the Withheld Action.

The Court of Appeals correctly held that the 180-day deadline of 21 U.S.C. § 355(j)(4)(A) is mandatory and found that the FDA has violated that deadline. App. 3a-4a. The APA provides that a "reviewing court *shall* . . . *compel* agency action unlawfully withheld," 5 U.S.C. § 706(1) (1988) (emphasis added), yet the Court of Appeals declined to afford Barr a remedy on the ground that relief is discretionary. App. 4a, 8a-9a. That ruling deprives Barr—and all other litigants aggrieved by agency disregard of statutory mandates—of an important right granted by Congress.

Barr sought relief under the APA as well as the All Writs Act, App. 11a (Pet. ¶ 1), but the Court of Appeals treated the two grounds as if they were identical. The court analyzed the entire case as one wherein the ultimate issue was whether to invoke its discretionary power

to issue a common law writ of mandamus. The Court of Appeals thus took the erroneous position that the APA, like the common law that is incorporated in the All Writs Act, does not require a reviewing court to compel unlawfully withheld agency action. If left uncorrected, this error effectively will nullify an important provision of the APA.

The decision whether to issue a common law writ of mandamus in cases of agency inaction is different from the decision whether to compel action under the APA. *See Davis Assocs., Inc. v. Secretary, Dep't of Hous. and Urban Dev.*, 498 F.2d 385, 388 (1st Cir. 1974); *Thompson v. United States Dep't of Labor*, 813 F.2d 48, 52 (3d Cir. 1987). Indeed, the *Thompson* decision suggests that consideration of whether APA-based relief is available must *precede* consideration of common law mandamus. *Thompson*, 813 F.2d at 52. That is, if APA relief is in order, the court need not even consider the availability of mandamus.

Common law mandamus is discretionary, *Whitehouse v. Illinois Central R.R.*, 349 U.S 366 (1955), even where a mandatory duty has been violated. *United States ex rel. Greathouse v. Dern*, 289 U.S. 352, 359 (1933). By contrast, where a finding of unlawful withholding has been made, relief under the APA is required. 5 U.S.C. § 706 (1) (1988); *Ass'n of Am. Railroads v. Costle*, 562 F.2d 1310, 1321 (D.C. Cir. 1977) (by implication). The judicial review provisions of the APA "set[] forth a simplified statement of judicial review *designed to afford a remedy for every legal wrong.*" H.R. Rep. No. 1980, 79th Cong., 2d Sess. (1946), *reprinted in* S. Doc. No. 248, 79th Cong., 2d Sess. 233, 250-52 (1946) (emphasis added).

The APA's use of the phrase "shall . . . compel" is consistent with this conclusion. The "use of the word 'shall' generally indicates a mandatory intent unless a convincing argument to the contrary is made." *Sierra Club v. Train*, 557 F.2d 485, 489 (5th Cir. 1977) (APA

case); *see Escoe v. Zerbst*, 295 U.S. 490, 493 (1935) (non-APA case). Ironically, the Court of Appeals followed this rule of construction in determining the meaning of "shall" in 21 U.S.C. § 355(j)(4)(A), *see* App. 3a-4a, but not in determining the meaning of the identical word in the APA.

The Senate report on the APA said that reviewing courts "must" compel unlawfully withheld agency action. S. Rep. No. 752, 79th Cong., 1st Sess. 27 (1945). The Senate and House managers of the legislation stated likewise during floor debate. 92 Cong. Rec. 2158 (1946) (statement of Sen. McCarran) ("courts are required to compel action shown to be unlawfully withheld"); 92 Cong. Rec. 5654 (1946) (statement of Rep. Walter) (courts "must compel action unlawfully withheld").

The courts also have found that the word "shall" in section 706 is mandatory. Section 706 "supersedes and makes irrelevant judicially fashioned concepts of the scope of judicial review of a federal agency's action, declared both prior and subsequent to its enactment. * * * Section 706 is mandatory by its terms." *Charlton v. United States*, 412 F.2d 390, 392 (3d Cir. 1969); *accord Estate of French v. FERC*, 603 F.2d 1158, 1167 (5th Cir. 1979) (court's "duty" to compel unlawfully withheld agency action); *Nader v. FCC*, 520 F.2d 182, 206 (D.C. Cir. 1975) (same).

Thus the APA requires that when a court determines that agency action has been wrongfully withheld, the court "shall . . . compel" that action. The Court of Appeals' rejection of this proposition was error.

II. The Court of Appeals Correctly Determined That the FDA Has Unlawfully Withheld the Action to Which Barr Is Entitled.

The APA requires the courts to remedy agency inaction in either of two instances—(1) where action has been unlawfully withheld and (2) where action has been un-

reasonably delayed. 5 U.S.C. § 706(1) (1988). These are *separate* bases for relief. Where—as here—a statutory mandate has been violated, the agency action has been "unlawfully withheld." *Environmental Defense Fund v. Costle*, 657 F.2d 275, 283 (D.C. Cir. 1981); *Sierra Club v. Thomas*, 828 F.2d 783, 793 (D.C. Cir. 1987). Only in the absence of a statutory deadline does the "unreasonable delay" test come into play. *Environmental Defense Fund v. Costle*, 657 F.2d at 283-84.

The Court of Appeals found that the FDA is violating the mandate of 21 U.S.C. § 355(j)(4)(A) to act on Barr's ANDAs within 180 days. App. 3a-4a. Such a violation constitutes unlawful withholding, not merely unreasonable delay. *Environmental Defense Fund v. Costle*, 657 F.2d at 283.[4] As such it entitles Barr to relief under the APA.

III. Where Congress Has Established Agency Priorities by Statute, Leaving to the Reviewing Court Only the Task of Instructing the Agency to Abide by That Statute, the Court Lacks Discretion Under the APA to Deny Relief.

The Court of Appeals found that FDA had unlawfully withheld action on Barr's ANDAs. The court nevertheless refused to act, on the theory that granting relief to Barr would cast the court in the role of reordering priorities that are for the agency to set. App. 7a. Even if the potential assumption of such a role were a proper basis for judicial inaction under the APA, nothing in this case required the Court of Appeals to play such a role. *Congress* established the FDA's priorities—at least insofar as ANDA processing is concerned—by enacting section 355(j)(4)(A). Barr asked only that the Court of

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[4] Any suggestion that unlawful withholding is merely unreasonably delay carried to extremes effectively would read the "unlawfully withheld" standard out of the APA. The courts must "'give effect, if possible, to every clause and word of a statute.'" United States v. Menasche, 348 U.S. 528, 538-39 (citation omitted) (1955); *accord* Heckler v. Chaney, 470 U.S. 821, 829 (1985).

Appeals do what the APA requires—enforce the mandatory directive of section 355(j)(4)(A) that the FDA rule on Barr's ANDAs within 180 days. The court's misinterpretation of the APA is sufficiently important, and its potential effect sufficiently harmful, as to require the intervention of this Court.[5]

CONCLUSION

The APA requires that a reviewing court compel agency action that has been unlawfully withheld. Having found such unlawful withholding, the Court of Appeals was required to "compel" the FDA to act. The court's contrary position denies that right not only to Barr but to all citizens who are entitled to have federal agencies adhere to mandatory statutory deadlines. A writ of certiorari should issue to review the judgment of the Court of Appeals for the District of Columbia Circuit.

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[5] Barr seeks a determination that when agency action has been unlawfully withheld, the reviewing court must "compel" that action. *See* 5 U.S.C. § 706(1) (1988). Such a ruling would not necessarily give Barr the right, on the 181st day after an ANDA is filed, to a court order requiring the FDA to rule on the ANDA forthwith. The APA requirement, although mandatory, presumably would not be violated if the reviewing court ordered the agency to establish and adhere to a specific schedule for meeting the agency's statutory responsibilities. *See, e.g.*, Ass'n of Am. Railroads v. Costle, 562 F.2d at 1321; Nader v. FCC, 520 F.2d at 182; *see also* N. Pipeline Constr. Co. v. Marathon Pipe Line Co., 458 U.S. 50, 88 (1982) (non-APA case); Buckley v. Valeo, 424 U.S. 1, 142-43 (1976) (same).

Respectfully submitted,

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July 1991

APPENDIX

APPENDIX

UNITED STATES COURT OF APPEALS
DISTRICT OF COLUMBIA CIRCUIT

No. 90-1402

IN RE BARR LABORATORIES, INC.,
Petitioner.

On Petition for Writ of Mandamus

Argued Feb. 19, 1991

Decided April 16, 1991

As Amended April 23, 1991

Eric L. Hirschhorn, with whom Bruce L. Downey, Washington, D.C., was on the brief for petitioners.

Jacob Laufer of the bar of the Supreme Court of the State of New York, pro hac vice, by special leave of the Court, with whom John M. Desiderio, James S. Rubin and Steven Shapiro, New York City, were on the brief, for intervenor.

Gerald C. Kell, Atty., Dept. of Justice with whom Stuart M. Gerson, Asst. Atty. Gen. and John R. Fleder, Washington, D.C., Director, Office of Consumer Litigation Dept. of Justice and Eric M. Blumberg, Rockville, Md., Associate Chief Counsel for Enforcement, Food and Drug Admin. were on the brief, for respondent.

Before SILBERMAN, WILLIAMS and RANDOLPH, Circuit Judges.

Opinion for the Court filed by Circuit Judge STEPHEN F. WILLIAMS.

STEPHEN F. WILLIAMS, Circuit Judge:

Barr Laboratories has filed a petition in this court, see *Telecommunications Research & Action Center v. FCC*, 750 F.2d 70, 74-79 (D.C. Cir. 1984) ("TRAC"), seeking a writ of mandamus to compel the Food and Drug Administration to act promptly in either approving or disapproving 23 of Barr's abbreviated new drug applications and abbreviated antibiotic applications (collectively, "generic drug applications"). Though we agree with Barr that FDA's sluggish pace violates a statutory deadline, we conclude that this is not an appropriate case for equitable relief. While judicial intervention could assist Barr, it would likely impose offsetting burdens on equally worthy generic drug producers, equally wronged by the agency's delay. Moreover, while prompt disposition of Barr's applications would benefit users of generic drugs, so would the disposition of other companies' applications, which relief for Barr would further delay.

* * * *

Under a 1984 amendment to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (1988), a producer of generic drugs may file applications that rely heavily on approved applications for "listed" (generally name-brand) drugs. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585. This expedited process permits generic drug applications to piggy-back on clinical findings that FDA has already embraced. Accordingly, the application must demonstrate, among other things, that the generic drug is the "bioequivalent" of the listed drug and that it is properly manufactured and labeled. See 21 U.S.C. § 355(j)(2)(A).

Congress specified that "[w]ithin one hundred and eighty days of the initial receipt of [a generic drug]

application . . . or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application." 21 U.S.C. § 355(j)(4)(A). Under regulations not challenged here, an applicant that files a "major" amendment to its application, either at the agency's behest or on its own initiative, is deemed to have consented to a new review period that may last up to an additional 180 days. See 21 C.F.R. §§ 314.60, 314.100(c) (1990).

Barr claims that the FDA has repeatedly violated the 180-day deadline in processing its generic drug applications. According to Barr, the agency has (in some cases) ignored the deadline altogether and (in others) improperly skirted it by waiting until the end of the 180-day period before provisionally "denying" the applications on the basis of spurious technicalities.

The FDA contests Barr's story only in the details. Whereas Barr calculates that the FDA took an average of 336 days to process past generic drug applications, Pet.Br. at 8, the FDA sets the figure at 262 days and estimates the response times for certain pending applications at between 389 and 669 days, Resp.Br. at 7. In other words, by the FDA's own account, its expected future delay will range from more than *double* the allotted time to nearly *quadruple*. Even in the FDA's view, the delays are severe. It explains the lag as the product of a personnel crisis that began in the summer of 1988, when scandal beset its generic drug division, forcing out some employees and diverting others from their usual work. See Burlington Declaration, Exhibit B, at 9-15.

Effectively conceding that it has violated the 180-day provision, the government answers that the deadline is only "directory". It reasons that because Congress did not specify a "consequence" for noncompliance, the provision—though seemingly mandatory—is only a kind of policy recommendation. The cases the government cites for this idea, e.g., *Brock v. Pierce County*, 476 U.S.

253, 259, 106 S.Ct. 1834, 1838, 90 L.Ed.2d 248 (1986); *Ralpho v. Bell*, 569 F.2d 607, 626-28 (D.C. Cir. 1977); *Fort Worth Nat'l Corp. v. FSLIC*, 469 F.2d 47, 58 (5th Cir. 1972); *Maryland Casualty Co. v. Cardillo*, 99 F.2d 432, 434 (D.C. Cir. 1938), are inapposite. All of them considered the separate problem of whether, as a consequence of missing a relevant statutory deadline, an agency loses jurisdiction over a case or issue; all (unsurprisingly) rejected that view. None of the cases considered the problem at issue here: whether an agency acts lawfully in ignoring a facially mandatory statutory deadline. In fact, the court in *Fort Worth* suggested that, in general, the "proper remedy" of a party seeking to enforce a statutory deadline is not to challenge the legitimacy of post-deadline agency actions, but "to apply for a court order compelling the [agency] to act." 469 F.2d at 58. That, of course, is just what Barr is doing.

The issue before us, then, is not whether the FDA's sluggishness has violated a statutory mandate—it has—but whether we should exercise our equitable powers to enforce the deadline. Equitable relief, particularly mandamus, does not necessarily follow a finding of a violation: respect for the autonomy and comparative institutional advantage of the executive branch has traditionally made courts slow to assume command over an agency's choice of ~~priorities~~. See, e.g., *In re Monroe Communications Corp.*, 840 F.2d 942, 946 (D.C. Cir. 1988).

Our leading case in this area, *TRAC*, identified six principles that have helped courts determine when mandamus is an appropriate remedy for agency delay:

> (1) the time agencies take to make decisions must be governed by a "rule of reason"; (2) where Congress has provided a timetable or other indication of the speed with which it expects the agency to proceed in the enabling statute, that statutory scheme may supply content for this rule of reason; (3) delays that might be reasonable in the sphere of eco-

> nomic regulation are less tolerable when human health and welfare are at stake; (4) the court should consider the effect of expediting delayed action on agency activities of a higher or competing priority; (5) the court should also take into account the nature and extent of the interests prejudiced by delay; and (6) the court need not "find any impropriety lurking behind agency lassitude in order to hold that agency action is 'unreasonably delayed.' "

750 F.2d at 80 (citations and internal quotes omitted). Here we may assume that Congress's 180-day deadline indeed supplies content for item one's "rule of reason", but a finding that delay is unreasonable does not, alone, justify judicial intervention. E.g., *In re Center for Auto Safety*, 793 F.2d 1346, 1354 (D.C. Cir. 1986).

TRAC's third factor (which overlaps with the fifth, at least in this context) asks whether the case is primarily about "human health and welfare" or "economic regulation". Here, at least, categorization of the values at stake is elusive. It is also largely irrelevant in light of *TRAC's* fourth consideration—the effect of relief on competing agency activities.

Barr's interest, we may assume, is entirely commercial. But it makes money getting useful drugs into the hands of sick people. Of course the "bioequivalents" of the drugs covered by these applications are, by definition, already available—but at a higher price, which makes the stake appear pecuniary. But for poorer people—the users for whom access to generic drugs is most important —a pecuniary saving on drugs may have important health benefits. The difference between sinking, say, 3% and 20% of one's income into pharmaceuticals spells a large difference in the range of economically accessible food and shelter.

The prevalence of health insurance hardly disposes of these complications. Much of the American population is

uncovered by medical insurance—predominantly, in all likelihood, people for whom access to generic drugs is especially important. Moreover, for those who do buy private health insurance, unavailability of generic drugs spells higher premiums and again less income available for food, shelter, and every other item that may contribute to health and well-being. Similarly, given limits on congressional and taxpayer willingness to subsidize health care, the unavailability of cheap drugs means fewer resources for other aspects of health care.

But the impact of the FDA's sluggish pace on the public health is effectively irrelevant in light of our analysis of *TRAC's* fourth factor, the effect of relief on competing agency priorities. Assuming constant resources for the generic drug program, a judicial order putting Barr at the head of the queue simply moves all others back one space and produces no net gain. Agency officials not working on Barr's matters presumably have not just been "twiddl[ing] their thumbs". See *Board of Trade v. SEC*, 883 F.2d 525, 531 (7th Cir. 1989). Perhaps Congress should earmark more funds specifically to the generic drug program, cf. Intervenor's Br. at 9, but that is a problem for the political branches to work out.

If Barr had shown that the FDA had singled it out for mistreatment, judicial relief would then advance the cause of equal treatment and, despite the lack of any immediate net advancement of Congress's policy objectives, could make sense. Our cases considering agency delay have often asked whether it was "egregious", see *In re Monroe Communications Corp.*, 840 F.2d 942, 946 (D.C. Cir. 1988); *TRAC*, 750 F.2d at 80; *Public Citizen Health Research Group v. FDA*, 740 F.2d 21, 34 (D.C. Cir. 1984), and especially shabby treatment of one applicant would seem exactly that.

In fact, Barr's reply brief alleges that the FDA *has* vindictively singled it out for especially bad treatment. Reply Br. at 9-10. If Barr had asserted this claim

initially, we would be able to assess whether it was worth a special factual inquiry. See *TRAC*, 750 F.2d at 78. Given the vague and secondhand character of Barr's claim (Barr emphasizes a lone congressman's suspicions), that seems improbable, but as Barr raised the issue only in its reply, respect for the adversary process makes it inappropriate to address the claim at all. See *Golden Pacific Bancorp. v. Clarke*, 837 F.2d 509, 513 (D.C. Cir. 1988); *Carducci v. Regan*, 714 F.2d 171, 177 (D.C. Cir. 1983). And absent this claim, we have no reason to think that judicial intervention would advance either fairness or Congress's policy objectives.

In short, we have no basis for reordering agency priorities. The agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way. Such budget flexibility as Congress has allowed the agency is not for us to hijack. In one of the exceptionally rare cases where this court has actually issued an order compelling an agency to press forward with a specific project, *Public Citizen Health Research Group v. Auchter*, 702 F.2d 1150 (D.C. Cir. 1983), we were persuaded, largely by agency concessions, that the project backed by plaintiff was plainly more "urgent" than any that the project's acceleration might retard. See *id.* at 1158. Nothing of the sort exists here. While Congress clearly intended a faster track for generic drug applications in general, it did not choose a super-priority for Barr, and it did not address the trade-off between strict compliance with the 180-day deadline and the FDA's disposition of its other projects with enough clarity to guide judicial intervention.

Barr tries to sidestep the resource-allocation issue by noting that the FDA itself has recently requested budget cuts from Congress. That request, filtered through the Office of Management and Budget, is the product of a complex set of policy tradeoffs; its size does not contradict

the FDA's claim that its resources are inadequate to satisfy an independently set timetable. In any event, even if the request reflected unsound judgment—a matter on which courts are completely unqualified to pass—the problems that flow from it are not ones that we can fix by reshuffling the agency's files.

The result would not change even if Barr could back up its insinuation that the FDA could act more efficiently if it tried. Reply Br. at 3, 7-8. We have no reason to think that a judicial decree advancing one applicant would cure FDA's incompetence, if it exists and even if it is severe. A court order could shift, but not lift, the burden that inefficiency inflicts on pharmaceutical suppliers and users. The agency could alleviate its own inefficiencies, perhaps through generic rulemaking, cf. *Heckler v. Campbell*, 461 U.S. 458, 103 S.Ct. 1952, 76 L.Ed.2d 66 (1983), or other simplifications of the review process—but judges have neither the capacity nor the authority to require such measures.

For its sixth item *TRAC* notes that "the court need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed." 750 F.2d at 80 (internal quotes omitted). But the issue of impropriety intersects with item four's sensitivity to the agency's legitimate priorities. Where the agency has manifested bad faith, as by singling someone out for bad treatment or asserting utter indifference to a congressional deadline, the agency will have a hard time claiming legitimacy for its priorities. Accordingly, the absence of bad faith, as here, is relevant to the appropriateness of mandamus. See *In re Monroe Communications Corp.*, 840 F.2d at 946-47.

* * * *

Congress sought to get generic drugs into the hands of patients at reasonable prices—fast. The record before us reflects a defeat of those hopes. There are probably remedies: more resources, more efficient use of those now

committed, elimination of the residual effects of the recently publicized scandals. For the reasons discussed, none is within our power, and a grant of Barr's petition is no remedy at all. For similar reasons, we see no point in maintaining constant supervision over the FDA's progress. We thus dismiss the suit, but invite Barr to refile should circumstances arise that would change the outcome of our analysis.

So ordered.

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 90-1402

BARR LABORATORIES, INC.,
Petitioner,

v.

LOUIS W. SULLIVAN, Secretary of Health and Human Services, DEPARTMENT OF HEALTH AND HUMAN SERVICES, JAMES S. BENSON, Acting Commissioner, Food and Drug Administration, FOOD AND DRUG ADMINISTRATION and CARL C. PECK, Director, Center for Drug Evaluation and Research,
Respondents.

PETITION FOR REVIEW OF AGENCY ACTION UNLAWFULLY WITHHELD AND UNREASONABLY DELAYED, AND FOR WRIT OF MANDAMUS

[Filed July 31, 1990]

Barr Laboratories, Inc. ("Barr") hereby petitions for review of agency action unlawfully withheld and unreasonably delayed by the respondents, the Department of Health and Human Services ("HHS"), HHS Secretary Louis Sullivan, the Food and Drug Administration ("FDA"), Acting FDA Commissioner James Benson, and FDA Center for Drug Evaluation and Research Director Carl Peck. Barr seeks a writ of mandamus requiring the respondents to act on the Abbreviated New Drug Applications and Abbreviated Antibiotic Drug Applications (collectively, "ANDAs") filed by Barr and enumerated in Exhibit 1 (filed under seal), all of which have been pending beyond the time limit established by the Federal Food,

Drug and Cosmetic Act. Barr also asks that the writ require the respondents to adhere to the statutory time limit as to all ANDAs that have been filed by Barr but have not yet exceeded such time limits and all ANDAs that Barr may file in the future. Finally, Barr asks that this Court retain jurisdiction over this proceeding to ensure that the respondents comply with the time limits established by law.

This petition does not ask the Court to review scientific issues or determinations. All that Barr seeks is to rectify the abject failure of the respondents to adhere to deadlines mandated by Congress for the benefit of the consuming public.

JURISDICTION AND VENUE

1. This Court has jurisdiction over this proceeding under section 505(h) of the Federal Food, Drug and Cosmetic Act ("Act") (21 U.S.C. § 355(h)) and the Administrative Procedure Act (5 U.S.C. §§ 701-706). In a case within its jurisdiction, this Court is authorized to issue a writ of mandamus by the All Writs Act (28 U.S.C. § 1651).

2. Venue in this Court is proper under section 505(h) of the Act (21 U.S.C. § 355(h)).

PARTIES

3. Barr is a corporation organized under the laws of the State of New York and has its principal place of business in Pomona, New York. Barr is engaged in the research, manufacture and marketing of pharmaceutical products.

4. Respondent Louis W. Sullivan is the Secretary of Health and Human Services. As such he is the federal officer responsible for ensuring compliance with the Act. In particular, he is charged by law with the approval or disapproval of certain types of drug applications, includ-

ing ANDAs, that manufacturers seek to market in the United States. Secretary Sullivan is sued in his official capacity.

5. Respondent HHS is the federal agency responsible for ensuring compliance with the Act. HHS is charged by law with the approval or disapproval of certain types of drug applications, including ANDAs, that manufacturers seeks to market in the United States.

6. Respondent FDA is an agency within HHS and is an agency of the United States Government. The relevant responsibilities of Secretary Sullivan and HHS under the Act have been delegated to the FDA.

7. Respondent James S. Benson is Acting Commissioner of the FDA and is the federal officer to whom the relevant responsibilities of Secretary Sullivan and HHS under the Act have been delegated. Acting Commissioner Benson is sued in his official capacity.

8. Respondent Carl C. Peck is the Director of the Center for Drug Evaluation and Research within the FDA and is the federal officer who has the operational responsibility for carrying out the relevant responsibilities delegated to acting Commissioner Benson. Director Peck is sued in his official capacity.

EXHAUSTION OF ADMINISTRATIVE REMEDIES

9. FDA rules and regulations provide no administrative review or relief for agency action on ANDAs that has been unlawfully withheld or unreasonably delayed.

THE ANDA PROCESS

10. Section 505(j)(4)(A) of the Act (21 U.S.C. § 355(j)(4)(A)) requires that "[w]ithin one hundred and eighty days of the initial receipt of an [ANDA] or within such additional period as may be agreed upon by [the respondents] and the applicant, [the respondents] shall approve or disapprove the application."

11. If the respondents decide to disapprove an ANDA, Section 505(j)(4)(C) of the Act (21 U.S.C. § 355(j)(4)(C)) requires that the respondents give the applicant 30 days to request a hearing and further requires that the respondents hold any requested hearing within 90 days after the expiration of the 30-day request period. Hearings held pursuant to subparagraph (C) must be "conducted on an expedited basis" and that the order thereon must "be issued within ninety days after the date fixed by [the respondents] for filing final briefs."

12. FDA requires specified pre-marketing safety and effectiveness testing of "new drugs" before such products legally may be marketed. A new or "innovator" drug is defined as "any drug [that] . . . is not generally recognized as safe and effective under the conditions prescribed, recommended, or suggested in the labeling." Act § 201(p) (21 U.S.C. § 321(p)). New drugs are approved by FDA pursuant to a New Drug Application ("NDA"). Innovator drugs also are referred to as "brand-name" drugs.

13. When a new drug is approved, the drug is placed on FDA's list of "Approved Drug Products with Therapeutic Equivalence Evaluations." The drug may then be duplicated or manufactured as a generic product.

14. The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. No. 98-417, 98 Stat. 1585) codified the ANDA process, which eliminates the need for safety and effectiveness data additional to that in the FDA-approved NDA for the brand-name drug. ANDAs are designed to ensure that generic duplicates containing the same active ingredients as the brand-name drug are equally safe and effective by proving that the two products are essentially the "same." The ANDA process is intended to provide significant reductions in the costs of prescription drugs.

15. FDA evaluates the degree of "sameness" of the generic and brand-name drugs through five principal

steps. In general, the ANDA must demonstrate that the generic product (1) contains the same active ingredients as the brand-name product, (2) matches the strength, dosage and route of administration of the brand-name product, (3) is "bioequivalent" to, or will produce the same therapeutic effect as, the brand-name drug (typically demonstrated through a "bioequivalence study"), (4) will be manufactured and handled so as to preserve its identity, strength, quality and purity, and (5) will utilize labeling essentially identical to that of the approved brand-name drug.

16. In contrast to the NDA approval process, FDA has not implemented standard operating procedures for reviewing ANDAs. Different FDA chemistry reviewers frequently focus upon different issues during ANDA reviews and weigh differently the importance of such issues. Virtually identical ANDAs hence may receive conflicting evaluations and FDA reviewers often proceed at radically different paces in reviewing similar ANDAs. Finally, FDA reviewers frequently delay ANDA approval for years by raising eleventh hour questions—often invalid—and requesting additional information—often irrelevant—about the ANDA.

17. When the legislation that was enacted as section 505(j)(4)(A) was pending before the Congress, FDA claimed that FDA would need a year to process each ANDA filed under the new rules. H.R. Rep. No. 857, pt. 1, 98th Cong., 2d Sess. 19 (1984). Congress nevertheless enacted the 180-day limit on FDA's consideration of ANDAs because Congress desired to ensure timely consumer access to generic drugs—which are far less expensive to purchase at retail than are the so-called brand name equivalents—and concluded that FDA could complete any necessary review within 180 days.

18. Indeed, Director Peck recently has stated that FDA can review a complete New Drug Application (NDA) (a significantly more involved process than for an ANDA)

within the 180-day statutory period. Food & Drug Reports, Apr. 16, 1990, at 9.

19. Despite the mandate of section 505(j)(4)(A) of the Act (21 U.S.C. § 355(j)(4)(A)), FDA's regulatory history is replete with institutional indifference to the 180-day deadline. A common practice is for FDA reviewers to notify the applicant as Day 180 approaches (or even after Day 180 has passed) that an ANDA is deficient in some minor, often irrelevant, insubstantial or erroneous, manner. This is accomplished by sending a "not approvable" letter pursuant to 21 C.F.R. § 314.120. In this fashion FDA purports to restart the 180-day clock at zero without taking substantive action on (or providing more than a cursory review of) an ANDA. This process can keep—and frequently has kept—an ANDA under FDA review for years.

FDA'S TRACK RECORD GENERALLY

20. Despite the Act's requirement that the respondents take action on ANDAs within 180 days after filing, the respondents consistently have failed to meet that deadline. As recently as May 1989, HHS advised a congressional committee that "relatively few [recent submissions] have gone over the 180-day period awaiting FDA review." *FDA's Generic Drug Approval Process (Part 1), 1989: Hearings Before the House Subcommittee on Oversight and Investigations, Committee on Energy and Commerce*, 101st Cong., 1st Sess. 82 (1989) (Supplement to Testimony of Larry D. Morey, Assistant Inspector General for Investigations, Department of Health and Human Services, May 10, 1990).

21. In May 1990, however, FDA's Center for Drug Evaluation and Research conceded that the number of ANDAs awaiting approval beyond the statutory limit had risen from 32 of a total of 891 pending in May 1989 to 588 of a total of 1018 pending a year later.

22. The same report reflected the fact that the average number of ANDAs approved per month had fallen from 56.7 in 1988 to 21.8 in 1989 and to only 5.8 during the first four months of calendar 1990.

23. Despite a sharp decline in the number of ANDAs being received by FDA—from more than 60 per month in May and June 1989 to less than 40 in each of the first four months of calendar 1990—the total number of ANDAs awaiting approval grew from 1027 to 1193 during the year ending in April 1990.

FDA'S TRACK RECORD ON APPLICATIONS FILED BY BARR

24. Barr's individual experiences with FDA have been consistent with the general statistics set forth above.

25. The average wait for the 81 ANDA approvals received by Barr from 1985 to date has been 336 days, and 28 of these have exceeded 400 days. For approvals received in 1990 the average processing time has been over 550 days.

26. Exhibit 1 hereto (being filed under seal because it contains confidential information) is a table of all pending Barr ANDAs that FDA has failed to approve or disapprove within the statutory period. The first element of the relief sought by Barr is final FDA action on these ANDAs.

27. By way of illustration, Barr sets out below the case histories of several Barr ANDAs that FDA has failed to approve or disapprove within the 180-day statutory period. Each of these ANDAs is supported by FDA's bioequivalence determinations, all required *in-vitro* data, and appropriate chemistry, manufacturing and labeling documentation.

Methotrexate Tablets (2.5 mg.) (ANDA 81-099)

28. FDA acknowledged receipt of Barr's ANDA for Methotrexate Tablets, a life-saving antineoplastic drug for which no other generic versions are available, on October 11, 1988. On February 22, 1989, a letter from FDA informed Barr that this ANDA was deficient. On March 2, 1989, Barr fully responded to FDA's letter. On April 17, 1989, FDA informed Barr that "from the bioequivalence point of view, [Barr] has met the requirements for *in-vivo* bioequivalence and *in-vitro* dissolution test [sic]."

29. In August 1989, FDA assured Barr that there was "no problem" with Barr's Methotrexate ANDA. On October 6, 1989, however, based on a misquotation and misapplication of FDA regulations concerning raw materials testing, FDA informed Barr that the ANDA was not approvable. Barr addressed these FDA errors in a November 1989 letter to FDA to which FDA never has responded. When Barr raised the issue again during a January 19, 1990, meeting with FDA, FDA claimed that the error had been typographical and said that it was "looking into" the matter. FDA has never formally retracted this mistake.

30. On July 2, 1990, FDA requested Barr's commitment to test for microbial contamination of raw materials on a specific schedule in addition to the testing required by FDA regulations. Barr provided the requested commitment to FDA by letter dated July 3, 1990.

31. This ANDA has been pending at FDA for over 600 days, yet the application has not yet been approved or disapproved by FDA.

Erythromycin Estolate Oral Suspension, USP, 125 mg. and 250 mg. per 5 mL (AADA 62-169)

32. Barr reactivated AADA 62-169 (for Erythromycin Estolate Oral Suspension, USP, 125 mg. and 250 mg. per

5 mL) with the submission of certain information on January 9, 1987. On April 16, 1987, FDA informed Barr that Barr's bioequivalence studies were acceptable. A November 24, 1987, FDA letter claimed that some samples of Barr's product were superpotent, although no abnormally high serum concentrations had been observed in clinical tests using the same lots. Barr nevertheless manufactured and submitted new samples, fully responding to FDA's comment letter on June 3, 1988.

33. In a March 10, 1989 letter, FDA again asserted that several of Barr's Erythromycin Estolate sample batches were superpotent. This FDA letter also requested data that Barr already had supplied in November 1988. A March 22, 1989, FDA letter acknowledged that sample testing by Barr and two outside laboratories had produced results complying with the specifications, but raised additional concerns about Barr's ANDA. Barr responded to these new concerns in submittals of March 27, March 30, and April 6, 1989. In Barr's meeting with FDA on June 16, 1989, and by an FDA follow-up letter dated June 30, 1989, Barr was informed that as soon as Barr had submitted three months stability data, FDA would expedite approval of this AADA. These data were submitted by Barr on June 28, 1989, more than one year ago.

34. On or about August 23, 1989, FDA informed Barr that the chemistry reviewer assigned to examine Barr's stability data for the Erythromycin Estolate AADA had requested to be taken off the review in early July and that FDA had granted the reviewer's unprecedented request. Because of vacation schedules, Barr was told, the first available person to review this application had only come back to work that week. Thus, from early July to late August 1989, Barr's application was simply left in limbo.

35. On November 9, 1989, FDA sent a letter to Barr stating that this product could not be approved for man-

ufacture at Barr's Pomona, New York, facility until Barr submitted certain data about that facility to FDA. Barr informed FDA on November 15, 1989, that Barr had submitted the requested information in June 1988. FDA never has acknowledged this error and in fact has informed Barr (January 19, 1990) that it must either conduct a new bioequivalence study or request a waiver for such study.

36. The November 9, 1989, FDA letter also resurrected FDA's "superpotency" claim, despite the fact that Barr had responded fully to that claim in March 1989.

37. FDA was compelled to hire an independent consultant to review the "superpotency" issue, and that consultant has found that Barr's Erythromycin Estolate product is not super-potent. Therefore, FDA has no valid basis for continuing to withhold approval of Barr's AADA.

38. Barr reactivated Barr's AADA for Erythromycin Estolate over 900 days ago, yet the application has not yet been approved or disapproved by FDA.

Erythromycin Ethylsuccinate Oral Suspension, USP, 200 mg. and 400 mg. per 5 mL. (AADA 62-161)

39. Barr reactivated AADA 62-161 (for Erythromycin Ethylsuccinate Oral Suspension USP (200 mg. and 400 mg. per 5 mL)) on December 23, 1986. FDA approved Barr's bioequivalence studies on August 24, 1987 (200 mg.) and September 3, 1987 (400 mg.). On September 23, 1987, Barr fully responded to FDA's comment letter of April 21, 1987. On September 27, 1988, Barr fully responded to FDA's comment letter of March 23, 1988, and submitted additional samples.

40. For the next 23 months Barr received no communication from FDA on this application. Then, on April 27, 1990, FDA requested data assuring the bioavailability of Barr's product manufactured at a facility different from that specified in Barr's application—data that Barr had submitted on September 23, 1987.

41. Barr submitted this AADA over 1260 days ago, yet the application has not yet been approved or disapproved by FDA.

Sulfamethoxazole and Trimethoprim Oral Suspension, USP, 200 mg./40 mg. per 5 mL (Cherry) (ANDA 72-785) and (Grape) (ANDA 72-827)

42. Barr filed these ANDAs on August 4, 1988 and September 9, 1988, respectively. On September 11, 1988, FDA acknowledged receipt of Barr's ANDA 72-785 for Sulfamethoxazole and Trimethoprim Oral Suspension (Cherry). On October 27, 1988, Barr fully responded to FDA's comment letter of September 21, 1988, which also found Barr's assay methodology and bioequivalence study acceptable. On February 27, 1989, Barr fully responded to FDA's February 2, 1989, comment letter. Barr has not heard from FDA on this ANDA in over 480 days. A similar calendar obtains with respect to Barr's ANDA 72-827 for Sulfamethoxazole and Trimethoprim Oral Suspension (Grape).

43. These ANDAs were received by FDA over 810 days ago, yet neither has been approved or disapproved by FDA.

Erythromycin Delayed-Release Tablets, USP, 333 mg.[1]

44. Prior to Barr's submission of AADAs for three potencies of Erythromycin Delayed-Release Tablets (500 mg., 333 mg. and 250 mg.), FDA agreed that a single bioequivalence study (on the 500 mg. strength) would suffice for all three AADAs because they were dose-proportional. Under this agreement, Barr would request a waiver of FDA's bioequivalence study requirements for the 333 mg. and 250 mg. products once Barr's 500 mg. product bioequivalence study had been approved.

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[1] This AADA was approved by FDA on May 15, 1990, and hence is not a subject of this petition. It is presented here, however, as a particularly egregious example of FDA's disregard for the 180-day statutory deadline.

45. Barr submitted AADA 63-028, Erythromycin Delayed-Release Tablets (333 mg. round), on June 16, 1988, and AADA 63-086, Erythromycin Delayed-Release Tablets (333 mg. capsule), on October 19, 1988. FDA approved Barr's 500 mg. product bioequivalence study on July 15, 1988. As agreed, Barr then requested bioequivalence study waivers for these two 333 mg. applications. On July 27 and September 2, 1988, Barr fully responded to FDA's letters of July 22 and August 29, 1988, which request additional information.

46. On October 14, 1988 (via telephone) and October 26, 1988 (by letter), FDA informed Barr that a bioequivalence study on Barr's 333 mg. tablets would be required, but that Barr could request expedited FDA review thereof.

47. FDA's laboratory thereafter tested Barr's exhibit samples using incorrect procedures. After Barr identified this error, Barr's samples were found acceptable.

48. On January 6, 1989, Barr submitted a bioequivalence study for the 333 mg. round tablet AADA. At FDA's suggestion, Barr requested expedited review of this study and of Barr's request for waiver of FDA's bioequivalence study requirement for the capsule-shaped 333 mg. tablet AADA. On February 11, 1989, Barr submitted additional bioequivalence study information.

49. On February 17, 1989, FDA accepted Barr's 333 mg. tablet bioequivalence study. In early April 1989 FDA "unofficially" informed Barr that Barr's bioequivalence study "waiver" for the capsule-shaped tablet had been granted but was under "re-review."

50. On April 17, 1989, FDA informed Barr that newly adopted FDA antibiotic bioequivalence study acceptance criteria would require FDA to reevaluate Barr's previously approved 333 mg. tablet bioequivalence study. On May 5, 1989, Barr submitted final package labeling. On July 3, 1989, Barr submitted Barr's production size master formula for both applications.

51. FDA's Director of Bioequivalence informed Barr on or about July 21, 1989 that Barr's bioequivalence study "waiver" request for the capsule-shaped 333 mg. tablet AADA was about to be approved. No such approval was forthcoming at or near that date.

52. In a telephone conversation on August 23, 1989, FDA informed Barr that although FDA's "re-review" of Barr's 333 mg. tablet bioequivalence study was complete, yet another new FDA directive prevented approval of Barr's applications. In a telephone communication on or about August 1, 1989, Director Peck threatened to rescind FDA's acceptance of Barr's 333 mg. tablets because Barr had (allegedly) improperly comparison-tested Barr's products with an Abbott rather than an Upjohn brand-name product. Remarkably, FDA originally had suggested that Barr use the Abbott product to test Barr's 500 mg. tablet in order to obtain FDA's waiver of bioequivalence study requirements on Barr's dose-proportional, lower strength forms. Moreover, FDA's Director of Bioequivalence had previously approved Barr's use of the Abbott product for these purposes.

53. These applications were pending with FDA for 719 days prior to approval.

Other Products

54. Barr has at least twenty-one pending ANDAs that have languished in FDA's hands significantly beyond the statutory 180-day period. Seven of these have been discussed in some detail above. Exhibit 1 hereto (being filed under seal) provides additional data on these twenty-one ANDAs.

FDA'S FAILURE TO PROVIDE A TIMELY HEARING

Conjugated Estrogens Tablets.
(ANDAs 89-634, 89-596, 89-633, 89-656 and 89-659)

55. The record of Barr's ANDAs for Conjugated Estrogens tablets (which are for five different strengths

of the same drug) generally reflects delays similar to those discussed above and set forth in Exhibit 1 hereto. FDA's consideration of these ANDAs also involved leaks of Barr's confidential information to a Barr competitor, a matter that is before District Judge Lamberth (*Barr Laboratories, Inc. v. Food & Drug Administration*, Civ. No. 88-3402 (RCL)) and hence is not made a subject of this petition.

56. In addition to the violation of the 180-day requirement, there is for Barr's Conjugated Estrogens ANDAs another violation of the Act—the requirements of section 505(j)(4)(C) (21 U.S.C. § 355(j)(4)(C)) that the hearing on an FDA decision to disapprove an ANDA be held within 120 days after the date of the disapproval letter and that the decision following such a hearing be issued within 90 days after the date fixed by FDA for filing final briefs.

57. FDA denied Barr's ANDAs for Conjugated Estrogens by letter dated September 30, 1988. Barr requested a hearing within the 30-day time limit established by section 505(j)(4)(C). Thereafter FDA and Barr agreed to suspend that request pending the outcome of a meeting of FDA's Advisory Committee on conjugated estrogens issues to be held in January 1989.

58. In March 1989, Barr submitted to FDA an additional pilot bioequivalence study to support approval of these ANDAs. FDA again denied Barr's ANDAs by letter dated October 11, 1989. Barr again requested a hearing within the 30-day statutory period.

59. On January 9, 1990, FDA sent Barr an "interim reply" informing Barr that FDA was "actively working" on preparing a hearing notice which FDA anticipated would be ready for publication in the *Federal Register* "in the near future." To date, FDA has not complied with its statutory obligations by giving Barr notice and opportunity for a hearing on FDA's denial of the Conjugated Estrogens ANDAs.

60. At the latest, the 120-day period during which a hearing must be held expired February 8, 1990. Thus far, more than 270 days after the disapproval, FDA has not even published the required notice of opportunity for a hearing.

CONCLUSION

61. The foregoing facts demonstrate that the congressional mandate that ANDAs be acted upon finally by FDA within 180 days of initial receipt is not being followed, and will not be followed in the foreseeable future, without the intervention of this Court. The same is true as to the hearing limits established by the Act.

62. This Court has authority to review FDA orders denying approval of ANDAs. Act § 505(h) (21 U.S.C. § 355(h)). FDA's failure to act on ANDAs filed by Barr effectively has thwarted this Court's jurisdiction. *See Roche v. Evaporated Milk Association*, 319 U.S. 21, 26 (1943). The appropriate remedy for such agency inaction is a writ of mandamus issuing from this Court. 5 U.S.C. § 706; 28 U.S.C. § 1651; *see Telecommunications Research and Action Center v. FCC*, 750 F.2d 70, 76 (D.C. Cir. 1984).

WHEREFORE, Barr respectfully requests that this Court—

(1) issue a writ of mandamus requiring the respondents to—

(A) promptly approve or disapprove the Barr ANDAs and AADAs set out in Exhibit 1, each of which was initially received by the respondents more than 180 days ago, as required by section 505(j)(4)(A) of the Act (21 U.S.C. § 355(j)(4)(A));

(B) promptly hold a hearing on Barr's disapproved ANDAs for Conjugated Estrogens Tablets, as required by section 505(j)(4)(C) of the Act (21 U.S.C. § 355(j)(4)(C)); and

(C) adhere to the time limits prescribed by section 505 of the Act with respect to all Barr ANDAs that are pending but have not yet passed the time limits, that may be filed in the future, or as to which hearings may be requested in the future;

(2) retain jurisdiction over this proceeding;

(3) award Barr its costs in this proceeding; and

(4) grant Barr such other relief as is appropriate.

Respectfully submitted,

/s/ Eric L. Hirschhorn
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